Assembly Bill No. 2155

Passed the Assembly August 28, 2006

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Chief Clerk of the Assembly

Passed the Senate August 23, 2006

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Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2006, at _____ o'clock ___M.

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Private Secretary of the Governor

CHAPTER _____

An act to add Section 25201.17 to the Health and Safety Code, relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 2155, Wolk. Hazardous waste: treatment: pharmaceutical activities.

(1) Existing law requires hazardous waste facilities, including, but not limited to, treatment facilities, to operate under hazardous waste facilities permits or other grants of authorization issued by the Department of Toxic Substances Control. Existing law exempts from the requirements relating to generators, tanks, and tank systems imposed pursuant to the hazardous waste control laws, and from the requirement to obtain a hazardous waste facilities permit, biotechnology elementary neutralization activities, as defined. A violation of the hazardous waste control laws is a crime.

This bill would additionally exempt pharmaceutical neutralization activities from those requirements, if specified conditions are met with regard to the pharmaceutical manufacturing or process development activities that generate or use the hazardous waste subject to the neutralization treatment and if the owner or operator of the pharmaceutical neutralization unit complies with specified requirements. The bill would require the owner or operator to establish and maintain documentation substantiating its compliance and would require the documentation to be available for inspection upon the request of the department or the Certified Unified Program Agency.

Since a violation of the requirements imposed by the bill upon the owner or operator of a pharmaceutical neutralization unit would be a crime, the bill would impose a state-mandated local program by creating new crimes.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 25201.17 is added to the Health and Safety Code, to read:

25201.17. (a) For purposes of this section, the following terms have the following meanings:

(1) "Pharmaceutical manufacturing or pharmaceutical process development activities" means activities conducted in North American Industry Classification System Code subgroups 325411 and 325412, to the extent they meet either of the following:

(A) Research, development, and production activities conducted in relation to an investigational new drug application or new drug application as set forth in Part 312 (commencing with Section 312.1) of, and Part 314 (commencing with Section 314.1) of, Subchapter D of Chapter 1 of Title 21 of the Code of Federal Regulations, that is filed with the United States Food and Drug Administration, or research and development activities conducted to support the future filing of an investigational new drug application or new drug application, or research, development, and production activities that are conducted in relation to a filing with a corresponding governmental authority in the European Union, Japan, or Canada that imposes similar requirements.

(B) The production of a pharmaceutical product, including starting materials, intermediates, and active pharmaceutical intermediates.

(2) "Pharmaceutical neutralization activities" means the deactivation of a material generated by, or used in, pharmaceutical manufacturing or pharmaceutical process development activities through the addition of a reagent, including, but not limited to, a caustic, before management of the material as a hazardous waste subject to this chapter.

(b) Pharmaceutical neutralization activities are exempt from any requirement imposed pursuant to this chapter, including any regulation adopted pursuant to this chapter, that relates to generators, tanks, and tank systems, and the requirement to

obtain a hazardous waste facilities permit or other grant of authorization from the department, except as otherwise provided in subdivision (c), if all of the following conditions are met:

(1) A permit is not required to conduct neutralization under the federal act pursuant to Section 264.1(g)(5) of Title 40 of the Code of Federal Regulations.

(2) The pharmaceutical manufacturing or pharmaceutical process development activities are conducted in accordance with the United States Food and Drug Administration's current good manufacturing practices, as set forth in Part 210 (commencing with Section 210.1) of, and Part 211 (commencing with Section 211.1) of, Subchapter C of Chapter 1 of Title 21 of the Code of Federal Regulations.

(3) The pharmaceutical neutralization activity occurs within a unit that meets the standards of a totally enclosed treatment facility, as defined in Section 260.10 of Title 40 of the Code of Federal Regulations and Section 66260.10 of Title 22 of the California Code of Regulations, that is physically connected to the reactor or vessel where the material being neutralized is created.

(4) The pharmaceutical neutralization activity is integral to the manufacturing process and occurs within the manufacturing process area and prior to the transfer of the material to a dedicated hazardous waste storage or treatment unit.

(5) If the pharmaceutical neutralization activity occurs at greater than 15 pounds per square inch gauge pressure, it shall occur within a unit that meets applicable American Society of Mechanical Engineers (ASME) standards for pressure rated vessels, including the ASME requirements for automatic pressure relief in the event of a system failure, including pressure relief valves, burst discs, or equivalent devices.

(6) The pharmaceutical neutralization activities do not raise the temperature of the hazardous wastes to within 10 degrees Celsius of the boiling point or cause the release of hazardous gaseous emissions, using either constituent-specific concentration limits or calculations.

(7) The temperature of any unit 100 gallons or larger is automatically monitored, the unit is fitted with a high-temperature alarm system, and, for closed systems, the

adding and mixing of in-process and neutralizing solutions are manually controlled.

(8) The pharmaceutical neutralization activity occurs within a facility that has design or engineering features, including, but not limited to, trenches, sumps, berming, sloping, or diking, designed to contain all liquid spills from pharmaceutical manufacturing process and neutralization units.

(c) An owner or operator of a pharmaceutical neutralization unit exempt under this section shall comply with all of the following requirements:

(1) The owner or operator shall successfully complete a program of classroom instruction or on-the-job training that includes, at a minimum, instruction for responding effectively to emergencies by familiarizing personnel with emergency procedures, emergency equipment, and emergency systems, including, where applicable, procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment, communications, or alarm systems.

(2) Within 10 days of commencing initial operation of the unit, or within any other time period that may be required by the CUPA, the owner or operator shall notify the CUPA of the commencement of the operation of the unit under the exemption made pursuant to this section. A CUPA is authorized to, and is required to, implement the requirements specified in this section. If the owner or operator is not under the jurisdiction of a CUPA, the notice shall be sent to the officer of the agency authorized, pursuant to subdivision (e) of Section 25404.3, to implement and enforce the requirements of this chapter listed in paragraph (2) of subdivision (c) of Section 25404.

(3) The owner or operator shall establish and maintain documentation to substantiate its compliance with all of the requirements and conditions of this section, and shall make the documentation available for inspection upon request of the department or the CUPA.

(d) Notwithstanding any other provision of law, all air emissions from a pharmaceutical neutralization unit shall be managed in accordance with the requirements of the local air pollution control district or air quality management district.

(e) All wastes generated as a result of pharmaceutical neutralization activities shall be managed as hazardous wastes in accordance with all applicable requirements of this chapter.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved _____, 2006

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Governor